

Application for Continuation of Approval Form

Please provide the following information to request continuation approval of a previously approved activity:

- 1) “Responsible MDCH Employee’s Name”** (MDCH person most directly responsible for the department’s role in this research):
- 2) “Responsible MDCH Employee’s Signature”** (required on the printed copies of this application to assure departmental responsibility for the protection of human subjects and adherence to MDCH IRB requirements): _____
The “Responsible MDCH Employee” is responsible for confirming information on this application with the Principal Investigator when he or she is not an MDCH employee.
- 3) MDCH IRB Archive Number** (assigned by IRB-leave blank unless known):
- 4) Title of Research Project** (title must be the same on the study protocol and informed consent):
- 5) Date this Application Received** (assigned by MDCH IRB): _____
- 6) What is the projected date for the completion of this research?**
- 7) How many study subjects have been accrued?**
- 8) Summarize any adverse events and/or unanticipated problems involving risks to subjects or others:**
- 9) Summarize any complaints or withdrawal of subjects from the study:**
- 10) Summarize any recent literature, interim findings and amendments or modifications that are relevant to the research:**
- 11) Summarize any relevant multi-center trial reports from Data Safety Monitoring Boards (DSMB) or Data Monitoring Committees (DMC).** This only applies to multi-center clinical trials. Such study-wide reports may satisfy the requirements of #4 without being directly submitted to the local IRB by the author.
- 12) Provide a copy of the current informed consent document and any newly proposed one** (indicate if attached): Attached ☐
- 13) Provide a brief summary of the protocol (less than 300 words) that describes the current status of the research as it relates to the involvement of human participants (e.g. enrollment closed, subjects have completed all research-related interventions, only long term follow-up remains, etc.)**